



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 28, 1995

MEMORANDUM

EPA ID No.: 432-INA Intercept Lawn Insect Granules
DP Barcode: D210071
Test Material: Permethrin 0.5% Granule

Chemical: 109701 Permethrin, mixed cis,trans (ANSI)

From: S. Oonnithan *Comm* 11/28/95
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

To: George LaRocca, PM 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Applicant: AgrEvo Environmental Health
95 Chestnut Ridge Road
Montvale, NJ 07645.

BACKGROUND

AgrEvo Environmental Health has submitted acute oral toxicity (MRID No. 434721-04), acute dermal toxicity (MRID No. 434721-05), primary eye irritation (MRID No. 434721-06), primary skin irritation (MRID No. 434721-07), and dermal sensitization (MRID No. 434721-08) studies on Permethrin 0.5% granule insecticide. The sample used for the testing was RUC #504 (Lot No. NB93-0098, 101B). The acute toxicity studies were performed by Stillmeadow, Inc., Sugar Land, TX.

FORMULATION FROM LABEL

<u>Ingredient(s)</u>	<u>% by wt.</u>
Permethrin, mixed cis,trans (ANSI)	0.5
Inerts	99.5
Total	100.0

USE DIRECTIONS

Intercept Lawn Insect Granules is recommended for the control of lawn insects, fleas, and ticks outdoors in residential areas. Repeated applications are made by broadcast treatment with a spreader to lawns, under shrubbery, and other ornamental and turf grass areas, band treatments are recommended around house foundation and spot applications are made to ant mounds and wasp nests.

RECOMMENDATION

81-1. Acute Oral: Category IV. The submitted study is acceptable.

81-2. Acute Dermal: Category IV. The submitted study is acceptable.

81-3. Acute Inhalation: Waived.

81-4. Eye Irritation: Category III. The submitted study is acceptable.

81-5. Skin Irritation: Category IV. The submitted study is acceptable.

81-6. Dermal Sensitization: Not a skin sensitizer to guinea pigs. The submitted study is acceptable.

LABELING

The following precautionary labeling statements were prepared by the LRS program.

Date: 11/28/95

LABEL REVIEW SYSTEM

ID #: 000432-00806

INTERCEPT LAWN INSECT GRANULES

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: 13
MRID No.: 434721-04
Author(s): J.O. Kuhn

Reviewer: S. Oonnithan
Report No.: 1139-94
Report Date: 08/24/94

Conclusion:

LD₅₀: Males/Females: >5000 mg/kg

Toxicity Category: IV

Classification: Acceptable

Quality Assurance (40 CFR §160.12): Included

Procedure (Deviations from §81-1): Rodent chow was used as a vehicle instead of water and a 24-hour feeding schedule was employed instead of gavage.

Testing Facility: Stillmeadow, Inc., Sugar Land, TX.

Test Material: Permethrin 0.5% Granule (RUC #504, Lot No. NB93-0098, 101B).

Test Animal: Rat; Sprague-Dawley

Age: Young adult

Weight: Males 239-287 g; Females 203-215 g

Source: Harlan Sprague Dawley, Inc., Houston, TX

Test Conditions: Attempts to dose the animals by gavage as a suspension of the powdered test material was unsuccessful. Therefore the test substance was mixed with pulverized rodent chow at 1:2 ratio and fed to fasted animals. All animals consumed the treated chow equivalent to a limit dose, over a 24 hour period.

Results:

Dosage	Number Dead/Tested		
	Males	Females	Combined
5000 mg/kg	0/5	0/5	0/10

Symptoms & Gross Necropsy Findings: All animals appeared normal and gained weight. The gross necropsy conducted at termination of the study revealed no observable abnormalities.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Product Manager: 13
MRID No.: 434721-05
Author(s): J.O. Kuhn

Reviewer: S. Oonnithan
Report No.: 1140-94
Report Date: 05/05/94

Conclusion:

LD₅₀: Males/Females: >5000 mg/kg
Toxicity Category: III
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure (Deviations from §81-2): None

Testing Facility: Stillmeadow, Inc., Sugar Land, TX.

Test Material: Permethrin 0.5% Granule (RUC #504, Lot No. NB93-0098, 101B).

Test Animal: Rabbit; New Zealand White
Age: Young adult (3-6 months)
Weight: Males 2.2-2.7 kg; Females 2.3-2.6 kg
Source: Ray Nichols Rabbitry, Lumberton, TX.

Test Conditions: The test material was mixed with water (8.18 ml/kg) and was then wrapped to the site with a 2-layer surgical gauze to maintain contact. Then the entire trunk was wrapped with a thin plastic film.

Results: There was no mortality.

Dosage	Number Dead/Tested		
	Males	Females	Combined
5000 mg/kg	0/5	0/5	0/10

Symptoms & Gross Necropsy Findings: Prominent in-life observations included diarrhea, decreased defecation, and flaking of the skin. All animals gained weight at the end of the study. Gross necropsy at termination revealed mottled brown kidneys in one animal.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: 13
MRID No.: None
Author(s): D. Johnson

Reviewer: S. Oonnithan
Report No.: None
Report Date: 11/08/95

Test Material: Permethrin 0.5% Granule

Data Waiver Request:

The registrant requested a waiver for this requirement, claiming that the subject formulation is a solid granule and under no circumstances, the product will form inhalable particles. The registrant submitted additional data (FAX dated 11/21/95), where the test material was ground in a ball mill for 24 hours (no details were provided) and analyzed for particle size. The particle size distribution data is given below.

Samples	Distribution (%) of particles at size (μm) ^a				
	<150	150-500	500-850	850-1000	>1000
Pail No. 7	2.2	16.8	26.6	14.2	40.3
Pail No. 8	1.5	11.9	20.4	12.8	53.5

^a Average of two analyses/sample.

Conclusion: The particle size distribution data indicate that little or no inhalable particles are formed after grinding the product in a ball mill for 24 hours. The submitted data is adequate for waiving the inhalation toxicity data requirement.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: 13
MRID No.: 434721-06
Author(s): J.O. Kuhn

Reviewer: S. Oonnithan
Report No.: 1141-94
Report Date: 04/27/94

Conclusion:
Toxicity Category: III
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure (Deviations from §81-4): None

Testing Facility: Stillmeadow, Inc., Sugar Land, TX.

Test Material: Permethrin 0.5% Granule (RUC #504, Lot No. NB93-0098, 101B).

Test Animal: Rabbit; New Zealand White; 3/sex
Age: Young adult (3-6 months)
Weight: NA
Source: Ray Nichols Rabbitry, Lumberton, TX.

Test Conditions: A subsample of test material was ground to a fine powder and 0.1 ml (\approx 44 mg) sample was placed in the eye. The treated eyes were not washed. The eyes were examined with a fluorescein solution 24 hours before treatment for defects and 24 hours after treatment for irritation until no staining of the cornea was observed.

Results: Conjunctival irritation cleared in 72 hours.

Observations	Number positive/Tested at			
	1 Hr	24 Hrs	48 Hrs	72 Hrs
Cornea Opacity	0/6	0/6	0/6	0/6
Iris	0/6	0/6	0/6	0/6
Conjunctivae: Redness	6/6	4/6	2/6	0/6
Chemosis	4/6	3/6	0/6	0/6
Discharge	1/6	1/6	0/6	0/6

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: 13
MRID No.: 434721-07
Author(s): J.O. Kuhn

Reviewer: S. Oonnithan
Report No.: 1142-94
Report Date: 05/03/94

Conclusion:

Toxicity Category: IV
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations from §81-5: None

Testing Facility: Stillmeadow, Inc., Sugar Land, TX.

Test Material: Permethrin 0.5% Granule, (RUC #504, Lot No. NB 93-0098, 101B)

Test Animal: Rabbit, New Zealand White
Age: Young adult (3-6 months)
Weight: NA
Source: Ray Nichols Rabbitry, Lumberton, TX.

Test Conditions: A 500 mg subsample was moistened with 0.8 ml water and introduced beneath a 2.5 x 2.5 cm two-layer surgical gauze patch and held in place with non-irritating tape. Then the entire trunk was loosely wrapped with a thin plastic film.

Results: No dermal irritation was found.

DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: 13
MRID No.: 434721-08
Author(s): J.O. Kuhn

Reviewer: S. Oonnithan
Report No.: 1143-94
Report Date: 06/30/94

Conclusion:

Toxicity Category: Not a Sensitizer

Classification: --

Quality Assurance (40 CFR §160.12): Included

Procedure Deviations from §81-6: None

Testing Facility: Stillmeadow, Inc., Sugar Land, TX.

Test Material: Permethrin 0.5% Granule (RUC #504, Lot No. NB 93-0098, 101B)

Positive Control: 2,4-Dinitro-1-chlorobenzene (DNCB)

Test Animal: Guinea pig; Hartley albino

Age: NA

Weight: Males - 342-381 g; Females - 315-388 g

Source: SASCO Inc., Madison, WI.

Test Method: Using Buehler's method, the test substance was screened for irritation at 25, 50, and 75% (w/v) in water and a 400 mg sample moistened with 0.4 ml water. The positive control (DNCB) was not screened, but based on prior experience, the following concentrations were picked for induction and challenge treatments.

- A. 400 mg Test material moistened with 0.4 ml water for induction and challenge
- B. 0.45% (w/v) DNCB in 80% ethanol for induction
- C. 0.15% (w/v) DNCB in acetone for challenge

Two groups of ten animals (5/sex) were subjected to induction treatments with the test substance (A) or positive control (B) at 0.4 ml/site, at weekly intervals for three weeks. Following a two week rest period, a single challenge application was made at a virgin site at 0.4 ml/site using the test substance (A) or positive control (C). Along with the challenge, two groups of ten animals (5/sex) were treated at the challenge dose of test substance or positive control, respectively as naive controls. Observations for skin reactions were made at 24, and 48 hours after induction and challenge.

Results: The results summarized below indicate that the test substance is not a skin sensitizer. The positive control tested to be a strong sensitizer.

Treatment	No. of animals with 0, 0.5, and ≥1 erythema scores (24 Hr) ^a	
	Permethrin 0.5% Granule	DNCB ^b
Induction #1	10, 0, 0	0, 1, 9
Induction #2	10, 0, 0	0, 0, 10
Induction #3	10, 0, 0	0, 0, 10
Challenge	10, 0, 0	0, 4, 6
Naive Control	10, 0, 0	10, 0, 0

^a Scoring: 0 = No reaction, 0.5 = very faint erythema, and ≥1 = faint to strong erythema with or without desquamation and eschar; sum of scores = total number of animals used.

^b Irritation data for DNCB from FAX dated 11/21/95.

ACUTE TOX ONE-LINER

EPA ID No.: 432-INA Intercept Lawn Insect Granules

DP Barcode: D210071

Chemical(s): 109701 Permethrin, mixed cis, trans (ANSI)

Applicant: AgrEvo Environmental Health

Test Material: Permethrin 0.5% Granule (RUC #504, Lot No. NB93-0098, 101B).

Date: November 28, 1995

G.L. #, Animal, Test Laboratory, Study #, Date	MRID No.	Results	Tox. Cat.	Core Grade ^a
81-1, Rat, Stillmeadow Inc., 1139-94, 08/24/94	434721-04	LD ₅₀ > 5000 g/kg	IV	A
81-2, Rabbit, Stillmeadow Inc., 1140-94, 05/05/94	434721-05	LD ₅₀ > 5000 g/kg	IV	A
81-4, Rabbit, Stillmeadow Inc., 1141-94, 04/27/94	434721-06	Conjunctival Irritation cleared in 72 hours	III	A
81-5, Rabbit, Stillmeadow Inc., 1142-94, 05/03/94	434721-07	Not a skin irritant	IV	A
81-6, Guinea Pig, Stillmeadow Inc., 1143-94, 06/30/94	434721-08	Not a sensitizer	--	A

^a A = Acceptable